UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,607	02/11/2002	Rozlyn A. Krajcik	4555-43U1	5919

570 7590 12/28/2004

AKIN GUMP STRAUSS HAUER & FELD L.L.P.
ONE COMMERCE SQUARE
2005 MARKET STREET, SUITE 2200
PHILADELPHIA, PA 19103-7013

EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/073,607	KRAJCIK ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-12 and 20-44* is/are pending in the application.

4a) Of the above claim(s) *9-12 and 20-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response filed October 6, 2004 have been received and entered into the application.

Action Summary

The rejection of claims 31- 37 under 35 U.S.C. 103(a) as being unpatentable over Drug Launches (6 June 1988) is being maintained for the reasons stated in the previous office action.

The rejection of claims 38-44 under 35 U.S.C. 103(a) as being unpatentable over Drug Launches as applied to claims 31-37 above, and further in view of Lurie (U.S.Patent No. 6,075,005) is being maintained for the reasons stated in the previous office action.

Response to Arguments

Applicants' arguments filed October 6, 2004 have been fully considered but they are not persuasive. Applicants essentially argue chlorohexidine (biguanide compound) that is commercially available in the liquid formulation taught by Drug Launches,

considered in the art to belong to the biguanide class of materials but it is not an insulin sensitivity increasing substance and instant invention is a method of treating alopecia that comprises administering to the mammal an insulin sensitivity increasing substance (ISIS) in an amount effective to treat the alopecia. This is not persuasive because the Instant specification provides **no structural guidance** of the biguanide compounds which are qualified for having an insulin sensitivity increasing substance (ISIS) and no **such structural guidance** was given in instant case, envisioned **functional limitation** (an insulin sensitivity increasing substance) does not distinguished the same (biguanide) compound utilized for the same effect (treatment of alopecia) taught by the prior art. Applicants next argue the Lurie reference is directed to hair growth compositions containing relaxin or a relaxin analog and an anti-androgenic agent and thus a person of skill in the art would not have been motivated to remove relaxin from the anti-androgenic agents and substitute instead an ISIS of the present invention, for elimination of relaxin from the formulation would, according to Lurie, render the formulation less effective since there is no indication, suggestion or motivation in either Lurie or Drug Launches that such combination could be successful. This is not persuasive because the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, it would have been obvious to one of ordinary skill in the art to combine STI, ARB with biguanide compound taught by Drug Launch because all the

components are well known individually effective for the treatment of alopecia. It would be expected that the combination of all the components would treat alopecia as well. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

In view of the above Office Action of October 6, 2004 is deemed proper and asserted with full force and repeated herein to obviate applicants' claims.

Claim Rejections - 35 USC § 103

Claims 31- 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drug Launches (6 June 1988).

Drug Launches teaches chlorohexidine (biguanide compound) is commercially available in a liquid formulation of 150ml, for the stimulation of hair growth and prevention of hair loss.

The prior does not expressly teach the administering to the mammal (human) and the active agent to reach an affected area of pilosebaceous apparatus.

It would have been obvious to one of ordinary skill in the art to employ chlorohexidine formulation taught by Drug Launches in mammal for the treatment of alopecia because chlorohexidine formulation is commercially available for the

stimulation of hair growth. One would have been motivated to employ the chlorohexidine formulation for the treatment of alopecia in order to achieve the therapeutic benefit of stimulation of hair growth in a mammal having alopecia condition. Moreover, the active agent (biguanide compound) taught by Drug Launches obviously reaches an affected area of a pilosebaceous apparatus upon administration to effectively stimulate the hair growth as taught by Drug Launches. Absent any evidence to contrary, there would have been a reasonable expectation of success in treating alopecia by preventing hair loss in mammal with easy access commercially available product taught by Drug Launches. The pharmaceutical formulations, e.g., topical, oral are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations.

Claims 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drug Launches as applied to claims 31-37 above, and further in view of Lurie (U.S.Patent No. 6,075,005).

The teachings of Drug Launches as applied as before.

Drug Launches does not teach the combination of chlorohexidine composition with STI, ARB or the activity-enhancing agent.

Lurie teaches anti-androgenic agents such as finasteride, spironolactone, flutamide or RU 58841 is useful for the treatment of hair growth or alopecia. (abstract).

It would have been obvious to one of ordinary skill in the art to combine STI, ARB with biguanide compound taught by Drug Launch because all the components are well known individually for treating alopecia. It would be expected that the combination of

components would treat alopecia conditions involving hair loss as well. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
December 15, 2004